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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,929	07/08/2004	Jeffrey C. Felt	32355.12.6.1.6	1494

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EXAMINER

ARAJ, MICHAEL J

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,929	FELT ET AL.	
	Examiner	Art Unit	
	Michael J. Araj	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/27/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

The drawings are objected to because Figures 12a, 12b, 12c, 12d, 12e, 13a, 13b, 14a, 14b, 14c, 15a, 15b, 15c, 16a, 16b and 16c need the label "Figure" or "Fig." And contain extraneous matter, e.g. "SIDE PLANE VIEW", "SECTION VIEW" and "SECTION B-B", etc., which is not permitted and should be removed. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: Figures 1a, 1b, 2a, 2b, 3a-3c, 4a, 4b, 5a, 5b, 6a-d, 7a-d, 8a-c, 9a-c, 11a-d, 12a-d, 13a, 13b, 14a-14c, 15a-15c and 16a-16c have no brief description.

Appropriate correction is required.

Claim Objections

Claim 22 is objected to because of the following informalities: Claim 22 states in lines 1-2, "a patella-femoral joint form suitable adapted to be", where it appears that "suitable" is in improper form and should be written as -- suitably --. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 10-15, 19-21 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 there exists an inconsistency in the language of the body of the claim, thus making the scope of the claim unclear. In lines 1-5, applicant recites "A system" with one or more polymeric components and with an "implant" being only functionally recited, e.g. "the system comprising one or more partially or fully performed polymeric components, adapted to be inserted and positioned at a joint to provide an implant...", thus indicating that the claim is directed to the subcombination, "A system". However, in

lines 6-12 of claim 1 and claims 19 and 29, applicant positively recites the implant as a part of the invention, e.g. "wherein the implant is a knee implant and provides a first major surface ... and a second major surface ... and the second major surface is provided with a femoral glide path ... in the form of a generally central depression ... the implant further comprising one or more tibial projections ...", thus indicating that the combination, system and implant, is being claimed. As such it is unclear whether applicant intends to claim the subcombination or combination or whether the component of the system and implant are the same thing. Applicant is hereby required to indicate to which, combination or subcombination, the claim is intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claim 1 will be considered as being drawn to the subcombination system.

In claim 1, line 1, "the creation or modification" lacks a prior antecedent. In line 7, "the tibial surface of the knee" lacks a prior antecedent. In line 8, "the femoral condyle" lacks a prior antecedent. In line 12, "the rim" lacks a prior antecedent.

In claim 3, lines 1-7, "the tibial projection(s)", "the posterior portion", "the tibial plateau", "the anterior-posterior dimension", "the medial-lateral dimension", "the posterior lip", "the thickness" and "the center" lacks a prior antecedent.

In claim 5, lines 2-3, "the joint site" lacks a prior antecedent.

In claim 7, line 2, "and/or" is indefinite because it is unclear what limitation such language places on the claimed subject matter.

In claim 8, line 2, "the joint site" and "the group" lacks a prior antecedent.

In claim 9, line 3, "the surgical field" lacks a prior antecedent

In claim 11, line 2 the phrase "optionally" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention or not, and the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In line 3, "and/or" is indefinite because it is unclear what limitation such language places on the claimed subject matter.

In claim 13, line 2, "and/or" is indefinite because it is unclear what limitation such language places on the claimed subject matter. In line 3, "the isocyanate-hydroxyl reaction" lacks a prior antecedent.

In claim 20, line 2, "the plane" lacks a prior antecedent. In line 3, "the corresponding shape" lacks a prior antecedent.

In claim 21, line 2, "the joint site" lacks a prior antecedent.

In claim 22, line 3, "the delivery" lacks a prior antecedent.

In claim 30, line 1, "the biomaterial" lacks a prior antecedent.

In claim 31, line 1, "the creation or modification" and "the wear surface" lacks a prior antecedent.

In claim 36, line 2, "and/or" is indefinite because it is unclear what limitation such language places on the claimed subject matter.

In claim 37, line 1, "the contoured surface" lacks a prior antecedent.

In claim 42, line 2, "and/or" is indefinite because it is unclear what limitation such language places on the claimed subject matter. In line 3, "the surgical field" lacks a prior antecedent.

In claim 43, line 2, "the shape" lacks a prior antecedent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 10-15, 17, 19-21, 28 and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,652,587. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent '587 anticipate the claims of this application.

Claims 1-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-79 of copending Application No. 10/121,455. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application '455 anticipate the claims of this application. Since the claims of this application are anticipated by the claims of the copending application '455, they are not patentable distinct from the claims of the copending application '455.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,20-22, 31-34, 41 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Averill et al. (U.S. Patent No. 3,728,742).

Averill et al. disclose a system comprising a fully formed polymeric component 16. With regard to the recitation "adapted to" it is noted that it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. In the instant case the component 16 can be inserted at a joint and it would constitute an implant. With regard to claims 20 and 21, it is noted that the system, as understood, of Averill et al. appears to be substantially identical to the system claimed, although produced by a different process, therefor the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Claim Rejections - 35 USC § 103

Art Unit: 3733

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 9-19, 27-29, 42, 44 and 45 are rejected, as understood, under 35 U.S.C. 103(a) as being unpatentable over Averill et al. (U.S. Patent No. 3,728,742).

Averill et al. disclose the claimed invention except for the dimensions of the preformed component or the glide path as set forth in claims 3, 9, 19, 28, 29 and 42. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the dimensions of the preformed component and the glide path of claims 3, 9, 19, 28, 29 and 42, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Averill et al. disclose the claimed invention except for the polymer being a polyurethane as set forth in claims 10-15 and 45 or other polymeric components as set forth in claims 16-18, 27 and 44. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use these materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 4-8, 23-26, 30, 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Averill et al. (U.S. Patent No. 3,728,742) in view of Fell et al. (U.S. Publication No. 2003/0060883).

Averill et al. disclose the claimed invention except for at least one ancillary component comprising of protrusions and integrated into, and partially extending from, the implant set forth in claims 4-7 and 35-38. Fell et al. teaches an extension from the prosthesis for fixation purposes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the prosthesis of Averill et al. with the ancillary component in view of Fell et al., in order to have an additional and alternate anterior fixation means. Averill et al. in view of Fell et al. discloses the claimed invention except for the specific materials as set forth in claims 23-26 and 39. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the system with these properties, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. With regard to claim 30, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the dimensions of the glide path as set forth in claim 30 of Averill et al. as modified by Fell et al., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. With regards to claim 8 and 40, Averill et al. in view of Fell et al. discloses the claimed invention except for the system comprising on or more separate components

Art Unit: 3733

including securing means. It would have been obvious to one having ordinary skill in the art at the time the invention was made to Describe modification and press the F9 key~, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Araj whose telephone number is 571-272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MJA


EDUARDO C. ROBERT
PRIMARY EXAMINER